AUG - 1 2003

K031387

Section I 510(k) Summary of Safety and Effectiveness

Applicant:

Hill-Rom Air Shields
330 Jacksonville Road
Hatboro, Pa. 19040
Registration No: 2510954

Contact Person:

Monica Ferrante
Ph 215-682-8691
Fax 215-682-8689

Device trade/proprietary name:

C2000e Isolette® Infant Incubator

Device common/usual/classification name:

Neonatal Incubator

Classification:

General Hospital
21 CFR 862.113
Neonatal Incubator, ???, Class II

Performance Standards:

None applicable

Predicate Device:

K960980 C2000 Isolette® Infant Incubator

Device Description

The C2000e is an enhancement to the currently marketed C2000 Isolette Infant Incubator originally cleared under 510(k) K960980. The features, functions, and performance of the C2000 incubator remain the same. The C2000e enhancements are additions to the C2000 product features. These additions are a horizontal rail system for attachment of accessories and a battery back up for the unit to maintain the controlled environment in

the event of a power failure or to move the infant within the hospital environment.

Intended Use

The Air Shields ISOLETTE® Infant Incubator is designed to care for the smaller premature baby as well as the healthier full term baby. It does this by providing a controlled environment, one in which the baby can be provided with the necessary care as well as being left undisturbed in the security of the incubator.

It is to this end that the product can be used in any department of the hospital that provides neonatal and infant care. One would typically expect the ISOLETTE® to be used in the NICU/SCBU (Neonatal Intensive Care Unit and/or the Special Baby Care Unit). The design lends itself to all levels of care in the NICU making it suitable for use in level I, II, III, and IV where applicable. Other departments would include the Step Down Nursery, Newborn Nursery and Pediatrics.

This device, when fitted with the battery backup feature, may be used to move the infant from one area of the hospital to another while maintaining the controlled environment.

Description of Modifications

The modifications to the device include a horizontal rail system for attachment of accessories and a battery back up for the unit to maintain the controlled environment in the event of a power failure or to move the infant within the hospital environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Ms. Monica Ferrante
Regulatory Affairs
Hill-Room Manufacturing, Incorporated
330 Jacksonville Road
Hatboro, Pennsylvania 19040

Re: K031387
Trade/Device Name: C2000e Isolette® Infant Incubator
Regulation Number: 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ, FPL
Dated: June 26, 2003
Received: June 27, 2003

Dear Ms. Ferrante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Direct
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section A SMDA Requirements

Indication for Use Statement

510(k) Number:

Device Name: C2000e Isolette® Infant Incubator

Indications for Use:

The Air Shields ISOLETTE® Infant Incubator is designed to care for the smaller premature baby as well as the healthier full term baby. It does this by providing a controlled environment, one in which the baby can be provided with the necessary care as well as being left undisturbed in the security of the incubator.

It is to this end that the product can be used in any department of the hospital that provides neonatal and infant care. One would typically expect the ISOLETTE® to be used in the NICU/SCBU (Neonatal Intensive Care Unit and/or the Special Baby Care Unit). The design lends itself to all levels of care in the NICU making it suitable for use in level I, II, III, and IV where applicable. Other departments would include the Step Down Nursery, Newborn Nursery and Pediatrics.

This device, when fitted with the battery backup feature, may be used to move the infant from one area of the hospital to another while maintaining the controlled environment.

This device is not intended for home use.

This is a prescription device.

(Please do not write below this line continue on another page if needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031387